

EXHIBIT 1

STATE OF NEW JERSEY In Re: DIGITEK LITIGATION -- March 27, 2009

SHEET 1

SUPERIOR COURT OF NEW JERSEY
BERGEN COUNTY
LAW DIVISION, CIVIL PART
DOCKET NO. L-917-09
APP. DIV. NO. _____

STATE OF NEW JERSEY)
)
) TRANSCRIPT
) of
IN RE:)
) CASE MANAGEMENT CONFERENCE
DIGITEK LITIGATION)
)

Place: Bergen Co. Justice Ctr.
10 Main Street
Hackensack, NJ 07601

Date: March 27, 2009

BEFORE:

HONORABLE JONATHAN N. HARRIS, J.S.C.

TRANSCRIPT ORDERED BY:

YONATHAN ZLOCZEWSKI, PARALEGAL, (Harris Beach, PLLC,
100 Wall Street, New York, New York 10005)

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1 just want you to be aware that there will be that
2 significant document production in the near future.

3 Now the other thing I would say, just give
4 you highlights of, we have -- we have worked I think in
5 good cooperation with the plaintiffs' counsel in this
6 case, in a number of meet and confers, several in
7 person and several by telephone.

8 What we have focused on -- let me tell you
9 what we've focused on and what we have -- what we have
10 not focused on simply because of time constraints. We
11 clearly have been focusing on issues on the protective
12 order and on the plaintiff fact sheets and the
13 defendant fact sheets.

14 What we really have not addressed at -- in
15 any significant depth, other than the barest of
16 discussions is we have not really talked to each other
17 about a case management order, a scheduling order. We
18 have not talked about electronic discovery. We have
19 not talked about culling terms. We have not talked
20 about preservation orders in any depth. All --
21 obviously preservation orders are in place in the
22 federal litigation.

23 But just to give you a flavor of what we have
24 done and what we have not done, that is I think the
25 highlights of the discussions between us and

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1 plaintiffs' counsel so far.

2 There was a brief reference, let me just
3 comment for one minute, on tolling agreements. We have
4 taken the position that we would not engage or we would
5 not enter into an across the board broad brush set of
6 tolling agreements.

7 However, we have told plaintiffs' counsel if
8 they get into a -- this -- this -- I guess it didn't
9 happen in this state but in other states there may be
10 statute of limitations issues coming up, and we have
11 told plaintiffs' lawyers that we have a group of cases
12 where you want to come to us, talk about specific cases
13 with the tolling agreement, we'll talk to you about
14 specific cases.

15 We don't want to do a broad across-the-board
16 agreement on tolling agreements. We would -- for
17 reasons as -- kind of similar to what you articulated,
18 we do see a value in knowing what the universe is and
19 getting -- getting that universe on file and knowing
20 what we're dealing with.

21 Then I think Ms. Relkin made brief reference
22 to the fact that -- you were talking about the testing
23 issue and whether any testing had been done. Ms.
24 Relkin made reference to the fact that she had heard
25 that tests had been done where out of spec results came

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1 back.

2 If indeed that has happened, nobody has -- no
3 plaintiffs' lawyer has provided that to us. What we
4 have done, Your Honor, is that we have -- many
5 plaintiffs' lawyers understandably want to know whether
6 they have any double-thick tablets.

7 These are very small tablets, so just by --
8 just to an untrained observer, it would be hard to tell
9 whether they were double thick or not. So we have gone
10 out to a number of plaintiffs' lawyers before who
11 wanted us to come and weigh and measure their tablets
12 to see if they had any double-thick tablets, all of
13 this on an informal discovery track, nothing formal,
14 and this is outside of New Jersey. I don't want -- I
15 want to make that clear.

16 We've visited probably the offices of 20
17 different plaintiffs' lawyers. We have -- we have not
18 yet seen any double-thick tablet. Now obviously you
19 heard the statement made to you this morning, well, we
20 may pursue a claim that a regular-size tablet without a
21 specification, that is going to be an extremely
22 difficult case to prove.

23 Frankly, I think the best way, the only way
24 really to prove that would be to test tablets and see
25 what the results -- what the results were. This

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1 litigation started out as, was at least generated,
2 initial filings were generated by the concept or the
3 thought that they were double-thick tablets out on the
4 market.

5 We believe our records will demonstrate, and
6 obviously the plaintiffs have a right to look at them,
7 they don't have to take my word for it, but we -- we
8 believe that the only double-thick tablets were one lot
9 and that they were found before they were -- they were
10 shipped to market.

11 So the bottom line is we have not --

12 THE COURT: Have you ever seen the double-
13 thick --

14 MR. DEAN: No, I have not.

15 THE COURT: -- tablet?

16 MR. DEAN: I have not.

17 THE COURT: Is that like the upside down
18 plane on the stamp, if you can find one, you're very --

19 MR. DEAN: Yeah, you've won -- you've won the
20 big prize. You asked a very --

21 THE COURT: Well, let me -- I apologize for
22 interrupting.

23 MR. DEAN: Sure.

24 THE COURT: Have any plaintiffs' counsel seen
25 this elusive double-thick tablet or any -- do you know

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1 of any experts who have, or doctors, or pharmacists, or
2 is it the quark?

3 MR. WEINKOWITZ: Your Honor, I'm not aware of
4 any -- that I have not looked at any tablets myself, so
5 I'm not aware of any. I'm not aware of whether anybody
6 else has.

7 But double thick from our perspective, is a
8 red herring. A pill can have more than or less than
9 the amount of the active ingredient in Digoxin even if
10 it's not twice as thick, and indeed, the FDA recall and
11 the announcement of the recall did -- went beyond just
12 double-thick tablets to talk about dosing.

13 So the defendants like to keep framing the
14 issues double thick, double thick, double thick. I
15 could have a bunch of tablets on my table and none of
16 them could be double thick but that's not the point.

17 THE COURT: Well, did -- did I hear you
18 represent before or if it was Ms. Relkin, I forget,
19 that there is forensic evidence, maybe incomplete and I
20 appreciate that, that would suggest that at least one
21 tablet somewhere, maybe more, whether it's double thick
22 or not is beside the fact, it has out-of-specification
23 dosage?

24 MR. WEINKOWITZ: Well, I'll tell you exactly
25 and Ellen can tell you what she heard. This is what I

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1 have heard in telephone discussions about this case,
2 that someone has done testing of the tab-- of Digitek
3 tablets, I don't know whether there were a plaintiff's
4 or not a plaintiff's, I don't know that, and that there
5 have been -- what has been discovered is too much
6 Digoxin and too little Digoxin, outside of what I
7 understand is the variances that are allowed to -- that
8 the tablets are allowed to have.

9 That -- I heard that. I don't know who's
10 done the testing. I don't even know who --

11 THE COURT: Wouldn't that be something that
12 I'm not suggesting you'd need that to file your
13 lawsuit, far from it, but wouldn't that be something
14 that you'd want to get your arms around as fast as
15 possible? Because if there are --

16 MR. WEINKOWITZ: What I --

17 THE COURT: Because if there are other
18 recognized ways of suffering Digoxin toxicity, it's a
19 question of risk and benefit analysis of going forward
20 with the lawsuit. I'm not trying to talk you out of
21 it, --

22 MR. WEINKOWITZ: Right.

23 THE COURT: -- far from it, --

24 MR. WEINKOWITZ: Right.

25 THE COURT: -- but I would think that if in

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1 fact there is this what's now anecdotal evidence out
2 there, plaintiffs would either want to urge me to get
3 the plaintiffs right away to be able to do their own
4 testing or collect from colleagues what this anecdotal
5 evidence is.

6 MR. WEINKOWITZ: And --

7 THE COURT: Don't take that as a criticism,
8 but --

9 MR. WEINKOWITZ: No, no, I understand, and
10 what I want as a plaintiff's lawyer to get my hands
11 around is what happened at that plant that wasn't in
12 FDA compliance, why were those pills recalled, what
13 testing was done, how much, what did they find. I
14 understand the --

15 THE COURT: Well, I must say that sounds like
16 the archetypical fishing expedition.

17 MR. WEINKOWITZ: Well, Your Honor, I --

18 THE COURT: I mean, you could -- you could
19 just as easily say about any drug manufacturer.

20 MR. WEINKOWITZ: Yeah, but not any -- any
21 drug manufacturers had --

22 THE COURT: Well, lots of people have adverse
23 drug effects --

24 MR. WEINKOWITZ: Yeah, but they didn't
25 have --

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1 THE COURT: -- and they go a plaintiff's
2 lawyer and say gee, I had a bad incident here, test it,
3 oh, my God, you have Coumadin poisoning, well, now I
4 want to go into the Coumadin plant, I want to check all
5 of their warfarin specifications.

6 I mean, it sounds absurd and silly, but I
7 think you'd want a little bit more than you've got
8 here. I'm not suggesting you're acting in bad faith
9 but, you know, a lot of whispers are in the wind in
10 this thing that don't really mean too much.

11 MR. WEINKOWITZ: Your Honor, in the scenario
12 -- I understand what you're saying in the scenario that
13 you came in. There -- here we have an FDA recall
14 involving tablets that had too much --

15 THE COURT: I must tell you that I don't put
16 much stock in an FDA recall as being anything.

17 MR. WEINKOWITZ: And we have a plant that
18 closed down and was cited twice for violations of good
19 manufacturing process, and that plant has never opened
20 back up, and in fact, the defendants had to recall all
21 of their generic drugs other than Digoxin from that
22 plant because of bad manufacturing process.

23 So with -- with all due respect, I think here
24 we have --

25 THE COURT: Well, if you think that you can

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1 convince a trier of the fact using that type of
 2 circumstantial evidence, I think that you need to re-
 3 think it, and I'm sure you wouldn't go to a jury with
 4 just that, you'd go to a jury with the specifics of the
 5 tablets. That's all I'm pointing out.

6 That ought to be something that plaintiffs
 7 were to get -- get involved with sooner rather than
 8 later. And I'm not suggesting, I'm not going to allow
 9 what I'll call free-ranging discovery, but I think it's
 10 starting to sound, and I'm just beginning to learn the
 11 subtleties and I'm probably going to misapprehend them
 12 today, that it may ultimately be counterproductive if
 13 in fact every ounce, every dollar that goes into
 14 defense costs potentially makes smaller the potential
 15 pool of a settlement.

16 You know, I think you really need to see what
 17 you've got rather than, you know, FDA did something,
 18 we're going to jump on that bandwagon. I mean, that
 19 could turn out to be a dead end. I don't want to hear
 20 anymore of this. I want to get back to this.

21 Mr. Dean.

22 MR. DEAN: Just a couple of more items, Your
 23 Honor. You asked a -- I think a question that really
 24 cuts to the heart of the litigation. The question you
 25 asked was -- of plaintiffs was is Digoxin toxicity

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1 caused by oversized tablets.

2 Well, the answer to that is Digoxin toxicity
 3 could well be caused by oversized tablets but the
 4 problem with the plaintiff, with the causation in this
 5 case is that Digoxin toxicity can also be caused by
 6 absolutely perfectly normal tablets.

7 You can have a tablet that's absolutely to
 8 specification and somebody can be taking it for let's
 9 say six months and they can be fine today and then may
 10 have a chance in their kidney function or may have a
 11 change in their metabolism and their Digoxin level can
 12 go up not because anything is wrong with the tablet but
 13 simply by what's happening within their body.

14 So their -- that, as you can appreciate,
 15 makes proof of causation in a specific case
 16 unbelievably -- unbelievably difficult. So the answer
 17 to your question could a double-sized tablet cause
 18 toxicity, I think if you took enough of them the answer
 19 is yes, but the conundrum here is that if you took
 20 perfectly normal tablets, under certain circumstances
 21 you can also end up with Digoxin toxicity.

22 I think in the material we provided to Your
 23 Honor we quoted from the package insert on -- on
 24 Digitek and it basically says you've got to look at
 25 what's going on in the patient, you can't be slandishly

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